IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NATIONAL STARCH AND CHEMICAL INVESTMENT HOLDING CORPORATION, PENFORD AUSTRALIA LTD., and PENFORD HOLDINGS PTY,

Plaintiffs,

C.A. No. 04-1443-GMS

v.

CARGILL, INC. and MGP INGREDIENTS, INC.,

Defendants.

DEFENDANTS' ANSWERING MARKMAN BRIEF

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Filed: October 7, 2005

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I. NATURE AND STAGE OF THE PROCEEDING

Defendants submit this answering brief in response to Plaintiffs' Opening Claim Construction Brief filed September 26, 2005. The parties dispute the meaning of the phrases "apparent amylose content" and "amylose content" as used in both the '840 and '454 patents. Although the parties agree that the phrases should be construed synonymously, they disagree over the appropriate construction. Plaintiffs have urged the Court to limit the claims to amylose content as measured solely by one exemplary and obscure method described in column 3 of the patents in suit. In contrast, Defendants argue that that terms should be construed more consistently with their ordinary meaning to include amylose content as measured by a variety of test methods—including at least any colorimetric iodine affinity analysis—that have been used in the art for decades to measure and report "apparent amylose content" and "amylose content." This is the construction expressly adopted by the examiner during prosecution and acquiesced to by the patentee. Because Defendants' construction is supported by the ordinary meaning of these phrases in the art and the intrinsic evidence, and Plaintiffs' construction is untenable in view of this evidence, the Court should adopt Defendants' construction.

II. SUMMARY OF ARGUMENT

1. As a starting point to the analysis, the claims use both "amylose content" and "apparent amylose content" without specifying any particular test method. Thus, the question then becomes how a person of ordinary skill in the art would interpret the phrases. A person of skill in the art would understand the phrases to include amylose content as measured by all of the well-known methods used for decades in the industry and the prior art, including the prior art cited by the examiner during prosecution of the patents in suit, to measure and report "apparent amylose content" and "amylose content." Moreover, nothing in the specification or prosecution history shows an intent by the patentee to narrowly limit the claims to the single, obscure test method recited in column 3 of the patents. On the contrary, the specification uses the phrases "apparent amylose

content" and "amylose content" to refer to several other test methods in addition to the method disclosed in column 3. In addition, nothing in the prosecution suggests that the patentee intended to narrow the claims to include only amylose content as measured by the method of column 3. On the contrary, the applicants acquiesced to the examiner's express construction that the claims *must be* read as referencing "amylose content" *as measured by colorimetric iodine analysis*, which includes many types of colorimetric iodine affinity methods used in the large body of relevant prior art.

2. In contrast, Plaintiffs have offered no evidence based on the ordinary meaning or intrinsic evidence to support their construction that limits the claims to one obscure test method appearing in column 3. Moreover, they do not explain their complete disregard for the examiner's express construction of the claims during prosecution, to which the applicants acquiesced. Plaintiffs' unsupported construction is particularly disconcerting given that it excludes virtually all well-known and accepted industry methods used to measure amylose content in the prior art. In advocating this construction, Plaintiffs are improperly attempting to erase decades of corn starch amylose content testing that would otherwise establish Defendants' noninfringement or be highly relevant and invalidating prior art.

III. CONCISE STATEMENT OF FACTS

The pertinent facts are set forth in Defendants' Opening *Markman* Brief. [See D.I. 38 at pp. 2-10.]

IV. ARGUMENT

A. Plaintiffs' Construction Ignores the Ordinary Meaning of "Apparent Amylose Content" and "Amylose Content" in the Art and Is Unsupported by the Intrinsic Evidence.

Although Plaintiffs properly emphasize the importance of the ordinary meaning, their proffered construction of "apparent amylose content" and "amylose content"—one limited to amylose content as measured only by a single, exemplary method disclosed in the patent specification—bears no resemblance to the ordinary and accustomed meaning

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of these terms. As Defendants explained in detail in their opening *Markman* brief, these terms have a long history in the high amylose corn starch art and have been used for over four decades to describe amylose content as measured by a variety of different analytical techniques, including numerous potentiometric and colorimetric methods.¹ Thus, a person of ordinary skill in the art reading the claims would interpret them to include amylose content as measured by any of these known methods.

Compared to the voluminous citations provided by Defendants in support of this ordinary meaning, Plaintiffs offer no support to equate the ordinary meaning of the disputed terms to their artificial construction. Instead, Plaintiffs argue that their construction is consistent with both the everyday English usage of the word "apparent" and the ordinary meaning of the phrases "apparent amylose content" and "amylose content" in the relevant art based on two conclusory and nonsensical assertions: (1) that amylose content cannot be determined merely by looking at the corn seed or starch, so a

See D.I. 39 at Ex. 7 (I.A. Wolff et al., "The Structure of New Starch of High Amylose Content," J. Chem. Soc., 77:1654-59, 1655 (1955) (measuring what the article refers to synonymously as both "amylose content" and "apparent amylose content" using both a 'potentiometric' and "blue value" (i.e., a type of colorimetric) method), Ex. 9 (F.R. Senti, "High-Amylose Corn Starch: Its Production, Properties, and Uses," in Starch: Chemistry and Technology, Chapter XXI at n.2 (1967) (using the term "apparent amylose content" in connection with several "analyses" upon which amylose content measurements are based), Ex. 14 (C.D. Boyer et al., "Changes in Starch Granule Size and Amylose Percentage During Kernel Development in Several Zea Mays L. Genotypes," Cereal Chem., 53(3):327-37 at 330 (1976) (measuring the "apparent amylose percentages" of starch samples using a particular blue value (i.e., a common type of colorimetric) method)), Ex. 5 (Virgil Fergason, "High Amylose and Waxy Corns," in Specialty Corns, Chapter 3 at p. 58 (1994) (referring to "various methods," including potentiometric iodine titrations and spectrophotometric (i.e., colorimetric or blue value) procedures, to measure the "apparent amylose" content)); Declaration of Courtney Nelson Wills in Support of Defendants' Answering Markman Brief dated October 7, 2005 (hereinafter "Nelson Wills Answering Decl.") at Ex. A (Edna M. Montgomery et al., "High Amylose Corn Starch Fractions" in 13 Die Starke at p. 215 (1961) (noting that the amylose content as measured by all iodine affinity procedures, which includes potentiometric and colorimetric procedures, should be considered "apparent amylose" content)), Ex. B (Jack C. Shannon & Douglas L. Garwood, "Genetics and Physiology of Starch Development" in Starch: Chemistry and Technology, Chapter III at p. 31 (2nd ed. 1984) (discussing blue value colorimetric and potentiometric iodine titration procedures and explaining that these procedures based on iodine complex formation should be considered "apparent amylose" measurements)); see also D.I. 38 at pp. 4-6 and the several references cited therein.

test must be applied to determine the amylose content that is "apparent" from that test and (2) that the "apparent amylose content" must be obtained using only the exemplary method set forth in column 3 of the patents in suit because this method is described as determining "apparent amylose" and results from this method are reported as the "apparent amylose content."

Plaintiffs' first assertion is nonsensical given that the everyday English usage of "apparent" is "open to view" or "appearing as actual to the eye," which is the exact opposite of how Plaintiffs attempt to use the term. [See Nelson Wills Answering Decl. Ex. C (Merriam-Webster's Collegiate Dictionary 59 (11th ed. 2004)); Ex. D (The American Heritage Dictionary of The English Language 85 (4th ed. 2000)).] Moreover, the phrases "apparent amylose content" and "amylose content" have no customary meaning in everyday English. They do, however, have a well-defined and customary meaning to a person of ordinary skill in the art—the relevant context for interpreting the patent claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1322 (Fed. Cir. 2005) (noting that a general-usage dictionary definition cannot overcome art-specific evidence of the meaning of a claim limitation). Both "apparent amylose content" and "amylose content" have long been understood by those of ordinary skill in the high amylose corn starch art to include amylose content as measured by a variety of potentiometric and colorimetric methods. [See supra n.1 (and references cited therein).]

Plaintiffs' second assertion also cannot support their unnecessarily narrow and strained construction. That the specification identifies an exemplary method in column 3 to determine the "apparent amylose" content does not mean that this one example should be used to define the claims to the exclusion of all other methods well-known in the art to measure "apparent amylose content." First, this usage of the phrase in the specification is not inconsistent with its ordinary meaning because it often appears in connection with a variety of different methods included under the umbrella of "apparent amylose content" measurements. Second, nothing else in the specification demonstrates an intent to

deviate from the ordinary meaning. See, e.g., In re Cruciferous Sprout Litig., 301 F.3d 1343, 1348 (Fed. Cir. 2002) (internal quotation omitted) ("The words of a claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor."). Instead, the specification merely sets forth the exemplary method in column 3 "[f]or the purposes of the description of the invention" to test the embodiments disclosed. [See D.I. 39 at Ex. 1 ('454 patent at col. 3, lines 6-8), Ex. 2 ('840 patent at col. 3, lines 4-6).] It does not state that the claims should be construed as limited to this method or that the phrases "apparent amylose content" or "amylose content" should be construed in a manner inconsistent with their long-standing, accustomed, and ordinary meaning, which includes amylose content as measured by a variety of methods.

The patent itself also uses the phrase "apparent amylose" in connection with other methods in addition to the exemplary method disclosed in column 3. For example, in column 2 of the common specification, the patent uses "apparent amylose" to describe the results reported in Cluskey et al. that were generated using two different methods—a potentiometric method and a colorimetric method—both of which vary somewhat from the method disclosed in column 3 of the patents. [See D.I. 39 at Ex. 1 ('454 patent at col. 2, lines 18-24), Ex. 2 ('840 patent at col. 2, lines 16-22), and Ex. 15 (J.E. Cluskey et al., "Fractionation and Characterization of Dent Corn and Amylomaize Starch Granules," Starch-Stärke, 32:105-09 (1980)).]

In addition, the specification also notes in column 1 in the "Background Art" that Australian patent document AU 45616/89 discloses an "amylose content" of up to 72%. [See D.I. 39 at Ex. 1 ('454 patent, col. 1, lines 31-34) and Ex. 2 ('840 patent, col. 1, lines 31-34).] This Australian patent document discloses "amylose content" based on the testing methods disclosed in a publication by Shannon and Garwood, which discusses amylose content as measured by both colorimetric blue value and potentiometric iodine titration methods. [See Nelson Wills Answering Decl. at Ex. E (Australian Patent

Document No. AU 45616/89 at 1-2 (referring to amylose contents disclosed in Shannon and Garwood)), Ex. B (Jack C. Shannon & Douglas L. Garwood, "Genetics and Physiology of Starch Development" in Starch: Chemistry and Technology, Chapter III at p. 31 (2nd ed. 1984) (discussing amylose content as measured by blue value colorimetric and potentiometric iodine titration procedures)).] Thus, the disputed phrases should not be limited to amylose content as measured by only the method disclosed in column 3 when the patents themselves use the phrases to refer to amylose content as measured by other methods.

Aside from these unfounded assertions, Plaintiffs point to nothing in the intrinsic evidence to support their construction. As just discussed, the ordinary meaning includes testing by a variety of potentiometric and colorimetric testing methods—a sharp contrast to Plaintiffs' attempt to arbitrarily limit the claims to a single test method. In addition, nothing in the specification indicates that the patentee intended to modify this ordinary meaning to limit the claims to Plaintiffs' overly narrow construction. *See Cruciferous Sprout Litig.*, 301 F.3d at 1348. Moreover, Plaintiffs completely ignore the prosecution history—an important part of the intrinsic evidence—in construing the claims. Thus, Plaintiffs' construction rests on unfounded and conclusory assertions that are unsupported by any intrinsic evidence.

B. Defendants' Construction Is Consistent with the Ordinary Meaning and the Intrinsic Evidence.

As explained in Defendants' opening *Markman* brief, both the ordinary meaning of "apparent amylose content" and "amylose content" in the relevant art and the intrinsic evidence strongly supports Defendants' construction. Defendants' analysis expressly recognizes that the ordinary meaning of the phrases includes amylose content as measured by a variety of methods, including potentiometric and colorimetric methods. [See D.I. 38 at pp. 4-6.] Similarly, the claims themselves use the phrases "apparent amylose content" and "amylose content" without incorporating any particular test

method. Moreover, the specification does not attempt to define the phrases in a manner inconsistent with their ordinary meaning and, in fact, uses the phrases in connection with more than one analytical method. [See id. at pp. 11, 14.]

Just as the claims and specification do not alter the ordinary meaning, nothing in the prosecution history warrants limiting the claims to amylose content as measured solely by the method disclosed in column 3 of the patents. On the contrary, the prosecution history reinforces that the claims must include amylose content as measured by more than one method.

During prosecution, the examiner rejected the claims over a large body of prior art disclosing "apparent" amylose content up to 85% as measured by a variety of methods, including various potentiometric and colorimetric methods. [See D.I. 39 at Ex. 4 at A67-68.] As representative of this large body of art, the examiner pointed to the 1967 publication by Senti disclosing corn starch containing 85% amylose as measured by colorimetric iodine affinity analysis. In making this rejection, the examiner expressly construed the claims as follows:

Interpreting the claims in light of the specification, the instant claims must be read as "... maize starch having an amylose content of more than 80%, as measured by colorimetric iodine analysis . . . "

[See id. (emphasis in original).] Because the claims "must be" construed in this manner, the examiner concluded they were invalid in view of the large body of prior art that included Senti. [See id.] In response, applicants did not challenge the examiner's express construction of the claims. Instead, they acquiesced to this construction, conceded that Senti was representative of a large body of invalidating art, and amended the claims to recite "apparent amylose content" greater than 90.1%. [See id. at A72-76.]

These events during prosecution support Defendants' construction in several ways. Because this large body of prior art included amylose content as measured by at least a variety of colorimetric iodine analyses, the claims at issue must also be considered

to recite amylose content as measured by a least these methods. Moreover, any disclaimer of claim scope during prosecution must be by clear and unambiguous disavowal, and nothing during the prosecution history narrowed the claim limitations from their ordinary meaning to amylose content as measured by the single method advocated by Plaintiffs. See, e.g., Superguide Corp. v. DirecTV Enter., Inc., 358 F.3d 870, 875 (Fed. Cir. 2004) (noting that although the prosecution history is always relevant to claim construction, it may not be used to infer the intentional narrowing of a claim absent the applicants' clear disavowal of claim coverage). On the contrary, Plaintiffs embraced the examiner's express construction of the claims that included amylose content as measured by any colorimetric iodine analysis. Thus, Plaintiffs cannot now in litigation attempt to avoid the concessions they made during prosecution to get the claims allowed and to construe the claims in a manner wholly inconsistent with the examiner's construction. Therefore, the intrinsic evidence as a whole supports Defendants' construction that the disputed phrases mean amylose content as measured by at least any colorimetric iodine analysis.

Contrary to Plaintiffs' suggestion, Defendants are not advocating for some "undefined, generic 'colorimetric iodine analysis" to "foreshadow[] some presentlyundisclosed, but carefully crafted test they hope to import into the claims to distort them and escape their embrace." [See D.I. 40 at p. 3).] On the contrary, Defendants' construction includes amylose content as measured by at least the numerous colorimetric methods well-known in the art at the time the patents in suit were effectively filed.

For example, the Corn Refiners Association, Inc. ("CRA") is a national trade association representing the corn refining industry of the United States, including member companies such as National Starch and Chemical Company, Penford Products Company, and Cargill, Incorporated. [See Nelson Wills Answering Decl. Ex. F. (http://www.corn.org and http://www.corn.org/membercompanies.htm (giving details "About the Association" and listing the "Member Companies").] The CRA and its

predecessors have been in existence since 1913 and provide technical services to assist the membership in developing quality systems for use by the industry. [See id.] The CRA has developed and publishes a compilation of analytical methods entitled "Analytical Methods of the Member Companies of Corn Refiners Association, Inc." to assist the corn refining industry and its customers. [See Nelson Wills Answering Decl. Ex. G (excerpts from the Analytical Methods of the Member Companies of Corn Refiners Association, Inc.).] Since 1975, this compilation has included an accepted method to measure the amylose content based on a spectrophotometric or colorimetric blue value technique. [See id. (B-26¹-B-26³ sets forth a colorimetric method that was accepted by the CRA in 1975 and subsequently revised in 1997); see also D.I. 39 at Ex. 11 (setting forth the Tentative Standard from 1975).] Whereas Defendants' construction embraces methods such as this industry standard—a standard backed for many years by a national trade organization to which both Plaintiffs and Defendants belong. In contrast, Plaintiffs' approach attempts to avoid these standard methods and limit the claims to the one obscure method disclosed in column 3 of the patents.

In addition to the corn refiners method, many other colorimetric methods were well-known in the art at the time the patents were effectively filed. While these colorimetric methods are numerous, they all involve the same basic steps of solubilizing the starch sample to be tested, mixing the sample with iodine, measuring the resulting blue color with a spectrophotometer, and comparing the results to a standard to obtain the "apparent amylose content." [See supra n.1 (listing several publications referring to colorimetric methods involving these same basic steps).] Thus, Plaintiffs cannot argue that Defendants base their construction on some undefined colorimetric method when it instead includes a large body of well-recognized test methods commonly used in the art for several decades prior to the time the patents were filed.

C. Plaintiffs' Strained Construction Is an Improper Attempt to Avoid a Large Body of Relevant Prior Art.

Plaintiffs' accusation that Defendants' construction attempts to import some undefined test method to escape the claims is ironic in view of their own proffered construction. Unlike Defendants' construction, it is in fact Plaintiffs' own construction that attempts to improperly import into the claims an arbitrary and obscure method to escape a large body of prior art disclosing amylose content measured by many wellknown and accepted test methods. Although contrary to the accustomed and ordinary meaning and unsupported by the claim language, specification, or prosecution history, Plaintiffs continue to pursue their untenable and overly narrow construction to avoid the many references that would otherwise be invalidating prior art.

Defendants are currently unaware of any publications aside from the patents in suit disclosing the particular method to which Plaintiffs' argue the claims should be exclusively limited. As explained in Defendants' opening brief, this obscure construction potentially allows Plaintiffs to engage in two improper tactics. First, to the extent that the method in column 3 of the patents gives results that somehow differ from the many other colorimetric methods well-known in the art, Plaintiffs could attempt to use this to their advantage to establish infringement according to the obscure method, even though other colorimetric methods show that Defendants do not infringe. Second, Plaintiffs could improperly attempt to distinguish otherwise invalidating prior art disclosing high levels of amylose content as measured by well-known methods solely because the references do not use the exact and obscure method disclosed in the patents. Both of these tactics are especially improper in light of Plaintiffs' admission during prosecution that such references would anticipate their claims. In fact, references such as these made up the large body of prior art that invalidated the original claims to starch with an amylose content of more than 80% and forced the applicants to amend their claims to include only starch having an amylose content of more than 90.1% or higher.

The threat of these tactics is particularly disconcerting in this case based on Plaintiffs' affirmative representation in their opening *Markman* brief that they are asserting all of the claims of both the '454 and '840 patents against Defendants. [See D.I. 40 at p. 5 ("All of the claims in each of the '454 and '840 patents are being asserted in this case.").] Despite the applicants' admission during the prosecution of the '840 patent that claims to starch having an amylose content of up to 85% were invalid over a large body of prior art, they now attempt to assert claims directed to that very subject matter. For example, claim 1 of the '454 patent recites maize seed containing starch having an amylose content of greater than 80%. Although this claim is invalid based on applicants' own admission during the later prosecution of the related '840 patent, Plaintiffs could now improperly attempt to distinguish this admitted prior art under their construction because the amylose contents disclosed in these references were not measured by the specific test in column 3 of the patents. This distinction was irrelevant during prosecution and should remain irrelevant in this litigation. See, e.g., Southwall Techs.,

² Defendants also have similar concerns regarding Plaintiffs' assertion of claim 4 of the '840 patent. Although Plaintiffs amended most members of this "Markush group" claim to recite an apparent amylose content of more than 90.1% (rather than an amylose content of more than 80%), the destructurized maize starch member still recites an apparent amylose of only more than 80%. See Manual of Patent Examining Procedure § 2173.05(h) (1994) (explaining Markush Group limitations). The failure to amend this one member invalidates the entire claim, especially considering applicants' admission during prosecution that the destructurized maize starch member in issued claim 1 must be amended from more than 80% to more than 90.1% to avoid a large body of otherwise invalidating prior art that included Senti. [See D.I. 39 at Ex. 4 at A72-76.] See Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003) (invalidating Markush type claims when the prior art disclosed one of the members of the Markush group); In re Wadlinger, 496 F.2d 1200, 1208 (C.C.P.A. 1974) (noting that each member of a Markush-type grouping must be allowable individually or the whole group fails); In re Schechter, 205 F.2d 185, 189 (C.C.P.A. 1953) ("If on examination of a generic Markush type claim, it be found that the applicant has included one or more members known to be old in the art for the same purpose as in the applicant's invention, the group in its entirety must fail of recognition in exactly the same manner as would have been the case had the group of elements of the claim been identified by a single term."). Although Plaintiffs may attempt to argue that the failure to amend this member was merely an oversight, they should still be precluded from asserting this facially invalid claim absent a certificate of correction. See Southwest Software, Inc. v. Harlequin Inc., 226 F.3d 1280, 1294-97 (Fed. Cir. 2000) (holding that a "certificate of correction is only effective for causes of action arising after it was issued" and that for

Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."). Thus, in addition to being unsupported by the ordinary meaning or intrinsic evidence, Plaintiffs' construction is an improper attempt to avoid otherwise admittedly invalidating prior art.

D. Claim Construction Should Be Limited to the Terms at Issue.

Although both Plaintiffs and Defendants agreed that only two claim limitations— "apparent amylose content" and "amylose content"—were in dispute in their Joint Preliminary Claim Construction Chart, Plaintiffs included in their opening brief a section on "Other Claim Terms" to ask for construction on several other terms. [See D.I. 36 (identifying only two terms in dispute); D.I. 40 at pp. 11-12.] Because these claims terms are not in dispute, it is improper to request that the Court construe them. See PSC Computer Prods., Inc. v. Foxconn Int'l., Inc., 355 F.3d 1353, 1357 (Fed. Cir. 2004) (internal citation omitted) ("Although an infringement analysis typically begins with claim construction, the district court here did not construe the claims ... because their meaning is not disputed."); Vivid Techs., Inc. v. Am. Science & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."); U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) (noting that claim construction is for "resolution of disputed meanings"). Therefore, the Court should ignore Plaintiffs' arguments regarding these "other claim terms."

causes of action arising before the certificate of correction becomes effective, the patent must be considered without the benefit of the certificate of correction). In addition, because any error and corresponding correction is not clear from the face of the patent itself, Plaintiffs cannot attempt to have the district court correct or revise the member to save the otherwise invalid claim. See Group One Ltd. v. Hallmark Cards, Inc., 407 F.3d 1297, 1303 (Fed. Cir. 2005) ("[T]he district court can correct an error only if the error is

evident from the face of the patent."); see also Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348, 1357 (Fed. Cir. 2003).

V. CONCLUSION

For the foregoing reasons, the Court should construe the claim limitations "apparent amylose content" and "amylose content" synonymously to include the amylose content as measured by at least any colorimetric iodine analysis.

Dated: October 7, 2005 FISH & RICHARDSON P.C.

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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2005, I electronically filed the

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